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| 10/508,746 | 03/19/2005 | Meong-Gun Song | 53850-10100 | 6244 |
| 25226 7590 07/14/2010 MORRISON & FOERSTER LLP 755 PAGE MILL RD PALO ALTO, CA 94304-1018 | | | | |
| EXAMINER | | | | |
| MILLER, CHERYL L | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/508,746

Applicant(s)

SONG, MEONG-GUN

Examiner

CHERYL MILLER

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 May 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5,6,13,15,16,22,23 and 26-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5,6,13,15,16,22,23,26 and 27 is/are rejected.
- 7) ☒ Claim(s) 28 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 1, 5, 6, 13, 15, 16, 22, and 23 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5, 6, 15, and 16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Each of the claims recite, "at least one" of the rings/bands having three or two makers. This is considered new matter as the specification and drawing always show *both* rings with three markers and *both* bands with two markers. "At least one" encompasses only one or both, broader than applicants have support for (applicants only have support for both-*no* embodiments are shown/disclosed with only one having markings). Applicant may want to consider claiming both rings comprising the three markers, or claiming for example, the inner ring comprising the three markers (and applicant could have a separate dependent claim requiring the outer ring to comprise the three markers). The same applies for the bands.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 5, 6, 15, 22, 23, 26, and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 requires each of an apparatus (preamble), annulus apparatus, and STJ apparatus. This is considered indefinite as all three are referred to as apparatus, in the dependent claims (for example claim 5 recites "The apparatus of claim 1), it is unclear which apparatus is being referred to. It is suggested to change "aortic annulus stabilizing apparatus" to --aortic annulus stabilizing device-- **or** change the preamble from "An apparatus" to --A device--. Claims 5, 6, 22, 26, and 27 depend upon claim 1 and inherit all problems associated with the claim.

Claim 5 recites the limitation "the continuous sinotubular junction stabilizing device" in line 4. There is insufficient antecedent basis for this limitation in the claim.

Claim 15 recites the limitation "the continuous sinotubular junction stabilizing device" in line 4. There is insufficient antecedent basis for this limitation in the claim.

Claims 22 and 23 each recite, "not have a graft or flexible tubular structure". This is indefinite. A flexible tubular structure could refer to the aortic lumen (wall of vessel). It is suggested applicant clarify by adding --prosthetic-- or --artificial-- prior to the word flexible.

Claims 26 and 27 each recite, "a material...is thinner than surrounding parts". This is unclear. If the entire ring/band is made of the same material, it is unclear how the "material" is thinner than the material. It seems applicant instead intended to claim --a portion...is thinner than surrounding portions-- or --wherein a material...is thinner in a central part than surrounding parts--.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 13, 15, and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Gabbay (US 6,264,691 B1). Gabbay discloses a treatment method (fig.7, 8) for treating an aortic valve having an aortic annulus (370), an STJ (340) and lumen (space therebetween) comprising implanting an inner discontinuous band (suture 344, parts of which are inside the lumen) inside the aortic lumen proximate the aortic annulus (see fig.8; is proximate 370), implanting an outer discontinuous band (342) outside the aortic lumen *proximate* the aortic annulus (proximate defined as near, close, the upper suture 342 being near or close the annulus 370), implanting an inner continuous ring (graft 306) proximate an interior surface of an STJ (is proximate 340) and implanting an outer continuous ring (girdle 300) proximate an exterior surface of the STJ (proximate 340). Gabbay discloses three spaced markers (considered commissures on girdle 300, inbetween apertures). Gabbay shows no additional graft between outer discontinuous band (suture 342) and outer continuous ring (girdle 300). If applicant were to use terminology more limited than “proximate” when describing the location of the bands and rings, this could seemingly overcome Gabbay. Currently, the outer discontinuous band is above the annulus, but still may be considered “proximate” to the annulus.

Claims 1, 6, 22, and 27 are rejected under 35 U.S.C. 102(c) as being anticipated by Lansac (US 2005/0065597 A1, cited previously). Lansac discloses an apparatus comprising an inner discontinuous band (2; fig.2) having two free ends, and outer discontinuous band (second 2 of another size; Lansac discloses a kit of various sizes, P0014) having two free ends, an inner continuous ring (1; fig.1) and an outer continuous ring (second 1; Lansac discloses a kit of various sizes, P0013) capable of encircling the inside and outside of an STJ (see figs.9-12). Although Lansac only uses bands and rings on the outside of the annulus and STJ (as seen in figs.9-12), Lansac does disclose a plurality of rings and bands provided to the surgeon of various sizes in order to achieve the best fit for a particular patient (P0013, P0014), thus the rings and bands may be considered *capable* of fitting the inside and outside of the annulus and STJ because the sizes are so close and a variety of sizes are provided. Vertical marks may be considered any of the marks seen in figure 2 (representing the individual threads). Lansac's apparatus does not include a connecting graft (fig.9-12). Lansac discloses the rings/bands to comprise a synthetic fiber (P0041, P0044).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lansac (US 2005/0065597 A1, cited previously) in view of Tremulis et al. (US 2003/0069593 A1, cited previously). Lansac discloses the aortic annulus apparatus substantially as claimed. Lansac

discloses two continuous ring stabilizers (1; fig.1; plurality, P0013) for the STJ (see fig.9-12) however does not disclose the stabilizers to have three spaced markers. Tremulis teaches in the same field of valve repair devices and methods, the use of three spaced markers on repair devices such that the surgeon can identify and orient as desired the device (P0048). It would have been obvious to one having ordinary skill in the art at the time the invention was made combine Lansac's valve stabilizing apparatus having, with Tremulis's teaching of placing markers on valve devices in order to provide increased identification and orientation during implantation of the device.

Allowable Subject Matter

Claim 28 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 16 and 26 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHERYL MILLER whose telephone number is (571)272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached at 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cheryl Miller/
Examiner, Art Unit 3738

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/Corrine M McDermott/

Supervisory Patent Examiner, Art Unit 3738